REMARKS

This communication responds to the Office Action of January 11, 2008 by amending claims 8 and 33 and adding new claims 57-60. No new matter has been added by these amendments or new claims.

Claim Rejections under 35 U.S.C. § 102

Claims 3, 5, 8, 10, 13, 14, 21 and 54 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,762,630 to Bley et al. ("Bley"). Applicants disagree. As an initial matter, the Examiner indicated that much of claim 8 (e.g. recitations involving the flow cross-section, the pliability, the positionability, and the moveability) was not given patentable weight due to certain recitations being part of the preamble. In an effort to further prosecution, the recitations have been placed in the body of the claim. Claim 8, as amended, is directed in part toward a cannula comprising "a selected flow cross-section over its entire length so as to maintain a constant hydrostatic pressure." In addition, the cannula is configured to "have a pliability that allows it to puncture a septum and a user's body; be positionable as near as possible to a desired target location; and be moved in any direction when inserted." Bley does not disclose these features.

Bley does not disclose a cannula that exhibits a selected flow cross-section as claimed. Bley discloses stylet 113 and hub 117. Fig. 1E of Bley shows stylet having a tapered distal end relative to hub 117. The tapered end results in a build-up of pressure at the distal end relative to other portions of stylet 113, and therefore the Bley stylet and hub cannot be configured to maintain a constant hydrostatic pressure as claimed in claim 8. Note: distal end of stylet 113 is not depicted in Figs 1B-1D as stylet 113 is disposed within catheter 111, thus hiding the distal end, and determining whether a constant hydrostatic pressure can be maintained in stylet 113 is not possible using Figs. 1B-1D.

Even if Bley exhibits a selected flow cross-section, Bley does not disclose a cannula configured to puncture a septum and a user's body as claimed. The stylet 113 and hub 117 in Bley in Figs. 1B-1E is introduced into a patient's vessel 101 after needle 109 pierces skin 100 and the introducer 103 is positioned in the skin. "A needle 109 is used to make the initial cut

through the skin 100 as shown in Fig. 1A. Once the needle 109, the introducer 103 and its sheath 107 are in the patient's vessel 101, the needle is removed and the introducer remains." Bley, col. 3, lines 40-45. Subsequently, stylet 113 and catheter 111 are provided in introducer 103 (see Figs. 1B-E). Thus, Bley does not disclose that stylet 113 is configured to puncture a septum and a user's body as claimed in claim 8.

Independent claim 8 is allowable for at least the above reasons. Dependent claims 3, 5, 10, 13, 14, 21 and 54 depend from claim 8 and are thus patentable for the same reasons as claim 8 and due to the additional limitations called for therein. Reconsideration and withdrawal of the § 102 rejection are requested.

Claim Rejections under 35 U.S.C. § 103

Claims 33, 37, 55 and 56 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,306,563 to Iwatschenko ("Iwatschenko") in view of U.S. Patent No. 4,835,248 to Bader et al ("Bader"). Applicants disagree. As with claim 8, claim 33 has been amended to place language from the preamble in the body of the claim.

Amended claim 33, like claim 8, is directed in part to a cannula comprising "a selected flow cross-section over its entire length so as to maintain a constant hydrostatic pressure." In contrast, Iwatschenko discloses a catheter or tubing 2 with a hollow passage 4. Holes 8 are provided in the catheter for substance to pass into the catheter. (e.g. the catheter is receiving the substance) Iwatschenko does not disclose "a selected flow cross-section" providing for "a constant hydrostatic pressure." The flow of substance in Iwatschenko encounters at least two cross-sections defined by hollow passage 4 and the holes 8, which are not disclosed as maintaining the same cross-section as hollow passage 4.

Amended claim 33, like claim 8, is also directed toward a cannula configured to "have a pliability that allows it to puncture a septum and a user's body." Iwatschenko discloses a catheter or tubing for insertion into body cavities. The Figure of Iwatschenko shows a rounded tip. Iwatschenko does not disclose "a pliability that allows it to puncture a septum and a user's body." There is no discussion in Iwatschenko of puncturing. Rather, Iwatschenko speaks of "introduction into body cavities." Specifically, Iwatschenko speaks of orally introduced catheters

and also discusses patients incapable of aiding introduction by swallowing. Iwatschenko appears to be directed at introduction through natural orifices, not through puncturing, and thus does not disclose a pliability that allows puncturing.

Amended claim 33 is also directed toward a cannula comprising "a water-absorbing material based on a polyamide of a first variable hardness that decreases in hardness upon water absorption."

The Examiner alleges that Bader, not Iwatshcenko, discloses a water-absorbing material. In previous Office Actions, the Examiner has repeated the same rejection asserting that Iwatschenko teaches "the cannula comprises a water-absorbing material" and has suggested that the only element missing in the Iwatschenko reference is that of a polyamide material. In reality, and as pointed out before, what Iwatschenko discloses is a dissolving material, not an absorbing material. In the current action, the rejection has not changed. However, in the response to arguments section, the Examiner now looks to Column 5, line 6 of Bader, not Iwatschenko, for disclosure of water absorption.

Iwatschenko discloses "a coating [which] may be soluble in water." Specifically, Iwatschenko states that "[i]t is particularly advantageous to use gelatine as the coating stiffening material. Gelatine is an inexpensive material easily worked with and soluble in water, therefore soluble in practically all body fluids within reasonable times."

Iwatschenko does not disclose "a water-absorbing material based on a polyamide of a first variable hardness that decreases in hardness upon water absorption." This is because the coating disclosed by Iwatschenko is a dissolving material, not an absorbing material.

Assuming for the moment, that a motivation can be found to combine Bader with Iwatschenko, Bader fails to remedy the deficiencies of Iwatschenko.

Bader is directed toward a biologically degradable polyamide for depot preparations having controlled release of the active compound and does not remotely concern catheters or cannulas. Thus, it does not disclose a cannula comprising "a selected flow cross-section over its entire length so as to maintain a constant hydrostatic pressure," nor does it disclose a cannula configured to "have a pliability that allows it to puncture a septum and a user's body."

Moreover, the combination of Bader with Iwatschenko for Bader's disclosure of a polyamide is improper. No motivation to combine the two references has been shown. First, Iwatschenko discloses a rigidizing coating. Thus, one of skill in the art would not need or be motivated to look to Bader for the biologically degradable polyamide because the need for a sufficiently stiff catheter would be satisfied by the rigidizing coating already known and disclosed by Iwatschenko. Moreover, no problems or drawbacks to the rigidizing coating of Iwatschenko are expressed. One of skill in the art would not look for an alternative. Second, Iwatschenko further states "It is particularly advantageous to use gelatine as the coating stiffening material. Gelatine is an inexpensive material easily worked with and soluble in water." Moreover, Iwatschenko states that "[g]elatine has a neutral taste so as to not be objectionable when orally introduced." Thus, not only has the need for a sufficiently stiff catheter been satisfied, the selected material, e.g. gelatine, has several expressly stated advantages. Nothing in the art of record teaches, suggests, or provides any motivation for replacing the inexpensive, neutral tasting rigidizing coating of Iwatschenko with that of the polyamide material of Bader, nor, according to Iwatschenko, would it be desirable to do so.

Dependent claim 55 was canceled in our response dated October 17, 2007 thus obviating the current rejection.

Independent claim 33 is patentable for at least the above reasons. Dependent claims 37 and 56 depend directly from claim 33 and are thus patentable for the same reasons as claim 33 and due to the additional limitations called for therein. For example, claim 56 recites an "initial hardness of said water-absorbing material equals that of a steel needle." In this particular case, the Examiner suggests that the hardness of a steel needle is dependent on the shape and size of the needle. To the contrary, the hardness of a material is a physical property unaffected by the size and shape of an article made from that material. Thus, claim 56 is patentable at least due to this additional limitation. Reconsideration and withdrawal of the § 103 rejection are requested.

Claims 3, 5, 8, 10, 11, 13, 14, 19-21 and 54 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Iwatschenko (US 4,306,563) in view of Bley (US 5,762,630). Applicants disagree.

The amendments and recitations of claim 8 have been discussed above regarding the § 102 rejection. For the same reasons raised with respect to claim 33, Iwatschenko fails to disclose all of the elements of claim 8. That is, Iwatschenko does not disclose "a selected flow cross-section" providing for "a constant hydrostatic pressure" nor does Iwatschenko disclose "a pliability that allows it to puncture a septum and a user's body."

Moreover, as acknowledged by the Examiner, Iwatschenko does not disclose a material that is thermally susceptible. Additionally, Iwatschenko does not disclose that the thermally susceptible material is a polymer.

As discussed above regarding the § 102 rejection, Bley does not disclose a selected flow cross-section providing for a constant hydrostatic pressure or a pliability that allows it to puncture a septum. Moreover, as with the improper combination of Iwatschenko with Bader, the combination of Bley with Iwatschenko is similarly improper. The Examiner has shown no motivation for one of skill in the art to replace the rigidizing coating and catheter of Iwatschenko with the thermally-softening stylet of Bley. In fact, the advantages disclosed in Iwatschenko regarding inexpensiveness and neutral taste would suggest an express lack of motivation to replace the rigidizing coating.

Independent claim 8 is allowable for at least the above reasons. Dependent claims 3, 5, 10, 11, 13, 14, 19-21, and 54 depend from claim 8 and are therefore patentable for the same reasons as claim 8 and due to the additional limitations called for therein. Reconsideration and withdrawal of the § 103 rejection are requested.

New Claims

New claims 57-60 have been added. Independent claim 57 is patentable as calling for "a water-absorbing material based on a polyamide of a first variable hardness that decreases in hardness after insertion and upon water absorption, yet remains intact." None of Iwatschenko, Bley, or Bader alone or in combination, teach, suggest, or provide any motivation for a water-absorbing material that decreases in hardness upon water absorption, but also remains intact. Dependent claims 58-60 depend from claim 57 and are patentable for the same reasons as claim 57 and due to the additional limitations called for therein. Entry and allowance are requested.

Conclusion

This response is being submitted on or before June 11, 2008 and an extension of time to respond until that date is hereby requested. The requisite fee should be charged to Deposit Account No. 04-1420. It is believe that no additional fees are due in connection with this filing. However, the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

The application now stands in allowable form, and reconsideration and allowance are requested.

Respectfully submitted,

DORSEY & WHITNEY LLP
Customer Number 74203

Date: June 11, 2008

By: _____
David E. Bruhn, Reg. No. 36,762
(612) 340-6317